

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST	)	
LABORATORIES HOLDINGS, LTD.,	)	
MERZ PHARMA GMBH & CO. KGAA,	)	
MERZ PHARMACEUTICALS GMBH, and	)	
ADAMAS PHARMACEUTICALS, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 14-508 (LPS)
	)	
AMNEAL PHARMACEUTICALS LLC,	)	
AMNEAL PHARMACEUTICALS OF NEW	)	
YORK, LLC, AMERIGEN	)	
PHARMACEUTICALS, INC., AMERIGEN	)	
PHARMACEUTICALS LTD. and MYLAN	)	
PHARMACEUTICALS INC.,	)	
	)	
Defendants.	)	

**PLAINTIFFS' ANSWER TO AMNEAL'S AMENDED COUNTERCLAIMS**

Plaintiffs Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.), Forest Laboratories Holdings, Ltd. (collectively, "Forest"), Merz Pharma GmbH & Co. KGaA, Merz Pharmaceuticals GmbH (collectively, "Merz"), and Adamas Pharmaceuticals, Inc. ("Adamas") (Forest, Merz, and Adamas collectively referred to herein as "Plaintiffs"), for their Answer to the Amended Counterclaims of Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC (collectively, "Amneal") (D.I. 57), hereby state as follows.

1. Plaintiffs admit that Amneal purports to bring counterclaims against Plaintiffs pursuant to 35 U.S.C. § 1, *et seq.*, and 28 U.S.C. § 2201, *et seq.* Plaintiffs, however, deny that there is any factual or legal basis for such counterclaims. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 1.

2. Counterclaim Paragraph 2 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Complaint alleges, *inter*

*alia*, that Amneal's submission of ANDA No. 205825 to the Food and Drug Administration ("FDA"), including its allegations pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), constitutes infringement of U.S. Patent No. 8,168,209, as corrected ("the '209 patent"), U.S. Patent No. 8,173,708 ("the '708 patent"), Claims 1-5 of U.S. Patent No. 8,283,379, as corrected ("the '379 patent"), U.S. Patent No. 8,329,752 ("the '752 patent"), U.S. Patent No. 8,362,085 ("the '085 patent"), and U.S. Patent No. 8,598,233 ("the '233 patent"). Plaintiffs further admit that Amneal's counterclaims purport to seek a declaratory judgment that U.S. Patent No. 8,039,009 ("the '009 patent"), the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid and not infringed by Amneal. Plaintiffs further admit that Amneal's counterclaims purport to seek a declaratory judgment that the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are unenforceable. Plaintiffs, however, deny that the Court has subject matter jurisdiction over any Amneal counterclaim directed to the '009 patent and Claims 6-15 of the '379 patent. Plaintiffs further deny that the Court has subject matter jurisdiction over any Amneal counterclaim asserted against Merz. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 2.

3. Counterclaim Paragraph 3 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the Court has subject matter jurisdiction over the Amneal counterclaims directed to the '209 patent, the '708 patent, Claims 1-5 of the '379 patent, the '752 patent, the '085 patent, and the '233 patent. Plaintiffs, however, deny that the Court has subject matter jurisdiction over any Amneal counterclaim directed to the '009 patent and Claims 6-15 of the '379 patent. Plaintiffs further deny that the Court has subject

matter jurisdiction over any Amneal counterclaim asserted against Merz. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 3.

4. Counterclaim Paragraph 4 states legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that venue is proper for purposes of this action. Plaintiffs further admit that the Court has personal jurisdiction over Plaintiffs for purposes of this action. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 4.

5. Upon information and belief, Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 5.

6. Upon information and belief, Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 6.

7. Plaintiffs admit that Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 7.

8. Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 8.

9. Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 9.

10. Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 10.

11. Plaintiffs admit the allegations in Amneal's Counterclaim Paragraph 11.

12. Plaintiffs admit that the '009 patent is titled "Modified Release Formulations Of Memantine Oral Dosage Forms" and admit that the '009 patent was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 18, 2011. Plaintiffs

further admit that a copy of the '009 patent was attached to the Complaint as Exhibit C. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 12.

13. Plaintiffs admit that the '209 patent is titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject" and admit that the '209 patent was duly and legally issued by the USPTO on May 1, 2012, with a certificate of correction issued on June 26, 2012. Plaintiffs further admit that a copy of the '209 patent, including its certificate of correction, was attached to the Complaint as Exhibit D. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 13.

14. Plaintiffs admit that the '708 patent is titled "Method And Composition For Administering An NMDA Receptor Antagonist To A Subject" and admit that the '708 patent was duly and legally issued by the USPTO on May 8, 2012. Plaintiffs further admit that a copy of the '708 patent was attached to the Complaint as Exhibit E. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 14.

15. Plaintiffs admit that the '379 patent is titled "Methods And Compositions For The Treatment Of CNS-Related Conditions" and admit that the '379 patent was duly and legally issued by the USPTO on October 9, 2012, with a certificate of correction issued on July 8, 2014. Plaintiffs further admit that a copy of the '379 patent, not including its certificate of correction which was issued after the filing of the Complaint, was attached to the Complaint as Exhibit F. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 15.

16. Plaintiffs admit that the '752 patent is titled "Composition For Administering An NMDA Receptor Antagonist To A Subject" and admit that the '752 patent was duly and legally issued by the USPTO on December 11, 2012. Plaintiffs further admit that a copy of the '752

patent was attached to the Complaint as Exhibit G. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 16.

17. Plaintiffs admit that the '085 patent is titled "Method For Administering An NMDA Receptor Antagonist To A Subject" and admit that the '085 patent was duly and legally issued by the USPTO on January 29, 2013. Plaintiffs further admit that a copy of the '085 patent was attached to the Complaint as Exhibit H. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 17.

18. Plaintiffs admit that the '233 patent is titled "Method For Administering An NMDA Receptor Antagonist To A Subject" and admit that the '233 patent was duly and legally issued by the USPTO on December 3, 2013. Plaintiffs further admit that a copy of the '233 patent was attached to the Complaint as Exhibit I. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 18.

19. Plaintiffs admit that the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are all listed in the FDA publication *Approved Drug Products With Therapeutic Equivalence Evaluations* ("the Orange Book") for Namenda XR®. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 19.

20. Upon information and belief, Plaintiffs admit that Amneal submitted ANDA No. 205825 to the FDA under 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, and sale of generic extended release capsule products containing 7, 14, 21, and 28 milligrams of memantine hydrochloride as the active ingredient ("the Amneal Generic Products") prior to the expiration of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752

patent, the '085 patent, and the '233 patent. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 20.

21. Upon information and belief, Plaintiffs admit that ANDA No. 205825 includes allegations pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Amneal Generic Products. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 21.

22. Plaintiffs admit that Forest and Adamas received written notification of ANDA No. 205825 and its allegations pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '009 patent, the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent. Plaintiffs deny that Merz received such written notification. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 22.

23. Plaintiffs admit that the Complaint was filed on or about April 21, 2014 and that this Complaint alleges, *inter alia*, that Amneal's submission of ANDA No. 205825 to the FDA, including its allegations pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), constitutes infringement of the '209 patent, the '708 patent, Claims 1-5 of the '379 patent, the '752 patent, the '085 patent, and the '233 patent. Plaintiffs further admit that Complaint Paragraph 33 states that "[r]elying on the representations set out in Amneal's notice of Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, Plaintiffs do not allege at this time that the Amneal Generic Products infringe the '009 patent" but that "[t]o the extent that discovery in this action demonstrates that assertion of the '009 patent against the Amneal Generic Products is warranted, Plaintiffs reserve the right to assert it." Plaintiffs, however, deny that there is an

actual, justiciable controversy over any Amneal counterclaim directed to the '009 patent at this time. Plaintiffs further state that Complaint Paragraph 33 states that "[f]or purposes of clarity, Forest and Adamas state that they are not asserting Claims 6-15 of the '379 patent against the Amneal Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient." Plaintiffs therefore deny that there is an actual, justiciable controversy over any Amneal counterclaim directed to Claims 6-15 of the '379 patent at this time. Plaintiffs further deny that there is an actual, justiciable controversy over any Amneal counterclaim asserted against Merz. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 23.

24. Plaintiffs admit that Amneal has denied that the commercial manufacture, use, offer for sale, or sale within the United States, or the importation into the United States, of the Amneal Generic Products would directly infringe, indirectly infringe, induce infringement of, or contribute to infringement of any valid and enforceable claim of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent, but Plaintiffs deny that there is any factual or legal basis for Amneal's denial. Plaintiffs further deny that there is an actual, justiciable controversy over any Amneal counterclaim directed to the '009 patent and Claims 6-15 of the '379 patent at this time. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 24.

25. Plaintiffs admit that Amneal has alleged that the claims of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, but Plaintiffs deny that there is any factual or legal basis for Amneal's allegations. Plaintiffs further deny that there is an actual, justiciable controversy over any Amneal counterclaim directed to the '009 patent and Claims 6-15 of the '379 patent at this

time. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 25.

26. Plaintiffs admit that there is an actual and justiciable controversy between Plaintiffs and Amneal with respect to Amneal's infringement of the '209 patent, the '708 patent, Claims 1-5 of the '379 patent, the '752 patent, the '085 patent, and the '233 patent as the result of Amneal's submission of ANDA No. 205825, which seeks FDA approval to engage in the commercial manufacture, use, and sale for sale of the Amneal Generic Products prior to the expiration of those patents. Plaintiffs deny that there is an actual, justiciable controversy with respect to the '009 patent and Claims 6-15 of the '379 patent at this time. Plaintiffs further deny that there is an actual, justiciable controversy over any Amneal counterclaim asserted against Merz. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 26.

27. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 26 as though fully set forth herein.

28. Plaintiffs deny that there is an actual, justiciable controversy regarding the '009 patent at this time. Plaintiffs lack sufficient knowledge or information sufficient to form a belief about the truth of the remaining allegations in Amneal's Counterclaim Paragraph 28 and deny them on that basis.

29. Plaintiffs deny that there is an actual, justiciable controversy regarding the '009 patent at this time. Plaintiffs lack sufficient knowledge or information sufficient to form a belief about the truth of the remaining allegations in Amneal's Counterclaim Paragraph 29 and deny them on that basis.



30. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 29 as though fully set forth herein.

31. Plaintiffs deny that there is an actual, justiciable controversy regarding the '009 patent at this time. Plaintiffs further deny the allegations in Amneal's Counterclaim Paragraph 31.

32. Plaintiffs deny that there is an actual, justiciable controversy regarding the '009 patent at this time. Plaintiffs further deny the allegations in Amneal's Counterclaim Paragraph 32.

33. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 32 as though fully set forth herein.

34. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 34.

35. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 35.

36. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 35 as though fully set forth herein.

37. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 37.

38. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 38.

39. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 38 as though fully set forth herein.

40. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 40.

41. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 41.

42. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 41 as though fully set forth herein.

43. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 43.

44. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 44.

45. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 44 as though fully set forth herein.

46. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 46. Plaintiffs further deny that there is an actual, justiciable controversy regarding Claims 6-15 of the '379 patent.

47. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 47. Plaintiffs further deny that there is an actual, justiciable controversy regarding Claims 6-15 of the '379 patent.

48. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 47 as though fully set forth herein.

49. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 49. Plaintiffs further deny that there is an actual, justiciable controversy regarding Claims 6-15 of the '379 patent.

50. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 50. Plaintiffs further deny that there is an actual, justiciable controversy regarding Claims 6-15 of the '379 patent.

51. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 50 as though fully set forth herein.

52. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 52.

53. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 53.

54. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 53 as though fully set forth herein.

55. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 55.

56. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 56.

57. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 56 as though fully set forth herein.

58. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 58.

59. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 59.

60. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 59 as though fully set forth herein.

61. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 61.

62. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 62.

63. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 62 as though fully set forth herein.

64. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 64.

65. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 65.

66. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 65 as though fully set forth herein.

67. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 67.

68. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 68.

69. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 68 as though fully set forth herein. Plaintiffs admit that Amneal purports to reallege and incorporate by reference the allegations set forth in Paragraphs 4 through 50 of its Affirmative Defenses. With respect to the allegations in Paragraphs 4 through 50 of Amneal's Affirmative Defenses, which purport to state defenses to

the claims set forth in Plaintiffs' Complaint, Plaintiffs deny that any such defenses exist or apply, and further respond to those Paragraphs as follows:

Affirmative Defense Paragraph 4: Plaintiffs admit that Dr. Gregory T. Went is a founder and Chief Executive Officer of Adamas and that he holds shares of Adamas stock. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 4.

Affirmative Defense Paragraph 5: Plaintiffs state that each of the patents-in-suit says what it says. Plaintiffs further state that the declarations by Dr. Went that were submitted to the USPTO during prosecution of the patents-in-suit say what they say. Plaintiffs further state that the prosecution histories for the patents-in-suit say what they say. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 5.

Affirmative Defense Paragraph 6: Plaintiffs state that the declarations by Dr. Went that were submitted to the USPTO during prosecution of the patents-in-suit say what they say. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 6.

Affirmative Defense Paragraph 7: Plaintiffs admit that during prosecution of the patents-in-suit, the applicants submitted declarations by Dr. Went dated November 5, 2010, April 2, 2012, and June 25, 2012. Plaintiffs state that these declarations say what they say. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 7.

Affirmative Defense Paragraph 8: Plaintiffs state that the November 5, 2012, April 2, 2012, and June 25, 2012 declarations say what they say. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 8.

Affirmative Defense Paragraph 9: Plaintiffs state that the November 5, 2012, April 2, 2012, and June 25, 2012 declarations say what they say. Plaintiffs further state that the declaration referred to by Amneal as the "Declaration submitted by Dr. Went in a related abandoned application" says what it says. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 9.

Affirmative Defense Paragraph 10: Affirmative Defense Paragraph 10 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that the prosecution histories of the patents-in-suit, including the Examiner's Statement of Reasons for Allowance of the '209 patent, say what they say. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr.

Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 10.

Affirmative Defense Paragraph 11: Affirmative Defense Paragraph 11 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs state that the prosecution histories of the patents-in-suit and the prosecution history of U.S. Application No. 12/757,824 ("the '824 application") say what they say. Plaintiffs further admit that Dr. Went was a named inventor on the '824 application. Plaintiffs further admit that the Utility Patent Application Transmittal Form for the '824 application states on its face that the '824 application was a continuation of prior application No. 12/512,701, and that the Examiner was Kendra D. Carter. Plaintiffs further admit that application No. 12/512,701 issued as the '209 patent, and that the Primary Examiner for application No. 12/512,701 was Sreeni Padmanabhan, and the Assistant Examiner for application No. 12/512,701 was Kendra D. Carter. Plaintiffs further admit that application No. 12/512,701 was filed on July 30, 2009, and issued as the '209 patent on May 1, 2012. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences

between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 11.

Affirmative Defense Paragraph 12: Affirmative Defense Paragraph 12 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated May 7, 2012 during prosecution of the '824 application. Plaintiffs further admit that a Notice of Allowance for the '209 patent issued March 16, 2012. Plaintiffs state that Dr. Went's May 7, 2012 declaration says what it says and that the prosecution history of the '824 application says what it says. Plaintiffs further admit that a Notice of Abandonment for the '824 application states that the application was abandoned on May 3, 2013. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 12.

Affirmative Defense Paragraph 13: Affirmative Defense Paragraph 13 contains legal conclusions and/or speculation, rather than factual allegations, to which no response is required. To the extent that a response is required, Plaintiffs state that the prosecution histories of the patents-in-suit say what they say. Plaintiffs further state that Dr. Went at all times fully complied



with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 13.

Affirmative Defense Paragraph 14: Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as

claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 14.

Affirmative Defense Paragraph 15: Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 15.

Affirmative Defense Paragraph 16: Plaintiffs admit that U.S. Patent No. 8,058,291 states on its face that it issued on November 15, 2011 from U.S. Application No. 11/399,879, filed April 6, 2006. Plaintiffs further admit that the '209 patent states on its face that it is a continuation in part of application No. 11/399,879, the '708 patent states on its face that it is a continuation in part of application No. 11/399,879, the '379 patent states on its face that it is a division of application No. 11/399,879, the '752 patent states on its face that it issued from a continuation-in-part of application No. 11/399,879, the '085 patent states on its face that it issued from a continuation-in-part of application No. 11/399,879, and the '233 patent states on its face

that it issued from a continuation-in-part of application No. 11/399,879. Plaintiffs further admit that Dr. Went filed a declaration dated November 5, 2010 during prosecution of the '291 patent. Plaintiffs state that the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 16.

Affirmative Defense Paragraph 17: Plaintiffs state that the prosecution history of the '291 patent, including the Office Action dated June 21, 2010, says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 17.

Affirmative Defense Paragraph 18: Plaintiffs state that the prosecution history of the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 18.

Affirmative Defense Paragraph 19: Plaintiffs state that Dr. Went's declaration dated November 5, 2010 says what it says and that the prosecution history of the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 19.

Affirmative Defense Paragraph 20: Plaintiffs state that the C106 clinical study is described in Dr. Went's declaration dated November 5, 2010, and that the declaration says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 20.

Affirmative Defense Paragraph 21: Plaintiffs state that the C106 clinical study is described in Dr. Went's declaration dated November 5, 2010, and that the declaration says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 21.

Affirmative Defense Paragraph 22: Plaintiffs state that the ME110 clinical study is described in Dr. Went's declaration dated November 5, 2010, and that the declaration says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 22.

Affirmative Defense Paragraph 23: Plaintiffs state that the prosecution history of the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 23.

Affirmative Defense Paragraph 24: Plaintiffs state that the prosecution history of the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 24.

Affirmative Defense Paragraph 25: Plaintiffs state that the prosecution history of the '291 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 25.

Affirmative Defense Paragraph 26: Plaintiffs admit that the applicants submitted a declaration by Dr. Gilman dated April 4, 2011 during prosecution of the '291 patent. Plaintiffs state that Dr. Gilman's declaration says what it says and that the prosecution history of the '291 patent says what it says. Plaintiffs are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Dr. Gilman in the first sentence of Affirmative Defense Paragraph 26 and on that basis deny them. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 26.

Affirmative Defense Paragraph 27: Plaintiffs state that the prosecution history of the '291 patent, including the Examiner's Statement of Reasons for Allowance, says what it says. Except

as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 27.

Affirmative Defense Paragraph 28: Plaintiffs admit that Application No. 12/512,701 was filed on July 30, 2009 and issued as the '209 patent on May 1, 2012. Plaintiffs state that the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 28.

Affirmative Defense Paragraph 29: Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 29.

Affirmative Defense Paragraph 30: Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 30.

Affirmative Defense Paragraph 31: Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated November 5, 2010 on December 21, 2011 during prosecution of the '209 patent. Plaintiffs further admit that the law firm of Wilson, Sonsini, Goodrich & Rosati prosecuted the '209 patent. Plaintiffs further admit that the applicants submitted a declaration by Dr. Gilman dated April 4, 2011 on December 21, 2011, during prosecution of the '209 patent. Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 31.

Affirmative Defense Paragraph 32: Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 32.

Affirmative Defense Paragraph 33: Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 33.

Affirmative Defense Paragraph 34: Plaintiffs deny that Dr. Went and his attorney ever acted with intent to deceive the USPTO and state that they at all times fully complied with the duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 34.

Affirmative Defense Paragraph 35: Plaintiffs state that the prosecution history of the '209 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 35.

Affirmative Defense Paragraph 36: Plaintiffs admit that application No. 12/757,819 was filed on April 9, 2010, and issued as the '708 patent on May 8, 2012. Plaintiffs state that the '708 patent says what it says. Plaintiffs further admit that the '708 patent states on its face that it is a continuation of application No. 12/512,701, which issued as the '209 patent. Except as

specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 36.

Affirmative Defense Paragraph 37: Plaintiffs state that the prosecution history of the '708 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 37.

Affirmative Defense Paragraph 38: Plaintiffs admit that the prosecution history of the '708 patent says what it says. Plaintiffs further admit that the prosecution history of the '708 patent contains a Notice of Allowance dated March 2, 2012. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 38.

Affirmative Defense Paragraph 39: Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 39.

Affirmative Defense Paragraph 40: Plaintiffs admit that Application No. 12/757,795 was filed on April 9, 2010 and issued as the '379 patent on October 9, 2012. Plaintiffs state that the '379 patent says what it says. Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated November 5, 2010 on December 14, 2011 during prosecution of the '379 patent. Plaintiffs further admit that the applicants submitted a declaration by Dr. Gilman dated April 4, 2011 on December 14, 2011, during prosecution of the '379 patent. Plaintiffs state that the prosecution history of the '379 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 40.

Affirmative Defense Paragraph 41: Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated April 2, 2012 on April 3, 2012, during prosecution of the '379 patent. Plaintiffs state that this declaration says what it says and that the prosecution history of the '379 patent says what it says. Plaintiffs further admit that Dr. Went submitted a declaration dated April 24, 2012 during prosecution of the '379 patent and that the declaration says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 41.

Affirmative Defense Paragraph 42: Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated April 2, 2012 on April 3, 2012, during prosecution of the '379 patent. Plaintiffs state that this declaration says what it says and that the prosecution history of the '379 patent says what it says. Plaintiffs further admit that Dr. Went submitted a declaration dated April 24, 2012 during prosecution of the '379 patent and that the declaration says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 42.



Affirmative Defense Paragraph 43: Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Plaintiffs further state that the prosecution history of the '379 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 43.

Affirmative Defense Paragraph 44: Affirmative Defense Paragraph 44 contains legal conclusions to which no response is required. To the extent a response is required, Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated April 2, 2012 on April 3, 2012, during prosecution of the '379 patent. Plaintiffs state that this declaration says what it says and that the prosecution history of the '379 patent says what it says. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 44.

Affirmative Defense Paragraph 45: Plaintiffs state that Affirmative Defense Paragraph 45 contains legal conclusions to which no response is required. To the extent that a response is required, Plaintiffs admit that the applicants submitted a declaration by Dr. Went dated June 25,

2012 during prosecution of the '752, '085, and '233 patents. Plaintiffs state that this declaration says what it says, and that the prosecution histories of the '752, '085, and '233 patents say what they say. Plaintiffs deny that Dr. Went and his co-inventors ever acted with intent to deceive the USPTO and state that they at all times fully complied with the duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 45.

Affirmative Defense Paragraph 46: Plaintiffs state that Dr. Went's May 7, 2012 declaration says what it says, and that the prosecution histories of the '824 application and the '752, '085, and '233 patents say what they say. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state

that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 46.

Affirmative Defense Paragraph 47: Plaintiffs state that Dr. Went's May 7, 2012 declaration says what it says, and that the prosecution histories of the '824 application and the '379, '752, '085, and '233 patents say what they say. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 47.

Affirmative Defense Paragraph 48: Plaintiffs state that the prosecution histories of the '824 application and the patents-in-suit say what they say and that Dr. Went's May 7, 2012 declaration says what it says. Plaintiffs admit that Dr. Went is a founder and Chief Executive Officer of Adamas and that he holds shares of Adamas stock. Plaintiffs further admit that Dr. Went is a named inventor on the patents-in-suit. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 48.

Affirmative Defense Paragraph 49: Plaintiffs state that each of Dr. Went's declarations says what it says. Plaintiffs deny that Dr. Went ever acted with intent to deceive the USPTO and state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's

declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 49.

Affirmative Defense Paragraph 50: Affirmative Defense Paragraph 50 contains legal conclusions and/or speculation, rather than factual allegations, to which no response is required. To the extent that a response is required, Plaintiffs state that the prosecution histories of the patents-in-suit and the '824 application say what they say. Plaintiffs further state that Dr. Went at all times fully complied with his duty of disclosure, candor, and good faith towards the USPTO. Plaintiffs further deny the materiality of any differences between the results reported for the ME110 clinical study in Dr. Went's declarations dated November 5, 2010, April 2, 2012, and June 25, 2012, and those reported for the ME110 clinical study in Dr. Went's declaration dated May 7, 2012. Plaintiffs further state that the claimed extended release forms of memantine in the patents-in-suit are, among other things, surprisingly well-tolerated compared to immediate release forms of memantine, such that significantly larger doses of the claimed extended release forms can be administered once daily without a concomitant increase in side effects. Plaintiffs further state that the data reported for the ME110 clinical study in Dr. Went's May 7, 2012 declaration fully support the inventions as claimed. Except as specifically admitted, Plaintiffs deny the allegations in Amneal's Affirmative Defense Paragraph 50.

70. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 70.

71. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 71.

72. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 71 as though fully set forth herein.

73. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 73.

74. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 74.

75. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 74 as though fully set forth herein.

76. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 76.

77. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 77.

78. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 77 as though fully set forth herein.

79. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 79.

80. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 80.

81. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 80 as though fully set forth herein.

82. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 82.

83. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 83.

84. Plaintiffs incorporate herein by reference their responses to the allegations in Amneal's Counterclaim Paragraphs 1 through 83 as though fully set forth herein.

85. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 85.

86. Plaintiffs deny the allegations in Amneal's Counterclaim Paragraph 86.

In response to Amneal's Demand for Judgment, Plaintiffs deny that Amneal is entitled to any relief whatsoever from Plaintiffs or the Court, whether as prayed for in Amneal's Amended Answer, Affirmative Defenses And Counterclaims or otherwise.

**GENERAL DENIAL**

Plaintiffs deny each and every allegation contained in Amneal's Amended Answer, Affirmative Defenses And Counterclaims that was not specifically admitted in Paragraphs 1-86 of this Answer.

**AFFIRMATIVE DEFENSES**

Plaintiffs allege and assert the following defenses in further response to Amneal's counterclaims, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. In addition to the affirmative defenses asserted below, Plaintiffs reserve the right to assert additional defenses, affirmative or otherwise, that become known during the course of discovery.

**First Affirmative Defense**  
**(Lack Of Subject Matter Jurisdiction With Respect To The '009 Patent)**

At this time, Plaintiffs have neither asserted nor threatened to assert the '009 patent against Amneal in connection with ANDA No. 205825. Plaintiffs stated in Paragraph 33 of their Complaint that "[r]elying on the representations set out in Amneal's notice of Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95, Plaintiffs do not allege at this time that the Amneal Generic Products infringe the '009 patent." Accordingly, no actual and justiciable controversy exists between the parties with respect to the '009 patent at this time, and no subject matter jurisdiction exists for the Court to adjudicate Amneal's asserted counterclaims with respect to the '009 patent.

**Second Affirmative Defense**  
**(Lack Of Subject Matter Jurisdiction With Respect To Claims 6-15 Of The '379 Patent)**

At this time, Plaintiffs have neither asserted nor threatened to assert Claims 6-15 of the '379 patent against Amneal in connection with ANDA No. 205825. Adamas is the owner of the '379 patent, and Forest is the exclusive licensee of the '379 patent with respect to commercializing pharmaceutical products containing memantine in the United States. Paragraph 33 of the Complaint states that "[f]or purposes of clarity, Forest and Adamas state that they are not asserting Claims 6-15 of the '379 patent against the Amneal Generic Products or any other generic extended release memantine hydrochloride product that contains memantine hydrochloride as the sole active ingredient." Accordingly, no actual and justiciable controversy exists between the parties with respect to Claims 6-15 of the '379 patent, and no subject matter jurisdiction exists for the Court to adjudicate Amneal's asserted counterclaims with respect to Claims 6-15 of the '379 patent.

**Third Affirmative Defense**  
**(Lack Of Subject Matter Jurisdiction With Respect  
To Counterclaims Asserted Against Merz)**

Paragraph 33 of the Complaint states that "Amneal's submission of ANDA No. 205825 to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent under 35 U.S.C. §271(e)(2)(A)" and that "if Amneal commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Amneal Generic Products, or induces or contributes to any such conduct, it would further infringe the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent under 35 U.S.C. §271(a), (b), and/or (c)." Adamas is the owner of the '209 patent, the '708 patent, the '379 patent, the '752 patent, the '085 patent, and the '233 patent, and Forest is the exclusive licensee of these



patents with respect to commercializing pharmaceutical products containing memantine in the United States. Merz does not own or license any of the patents asserted against Amneal in this action. Accordingly, no actual and justiciable controversy exists between Merz and Amneal with respect to the patents-in-suit, and therefore no subject matter jurisdiction exists for the Court to adjudicate Amneal's counterclaims asserted against Merz.

**Fourth Affirmative Defense**  
**(Failure To State A Claim)**

Each of Amneal's asserted counterclaims fails to state a claim upon which relief can be granted.

**PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs pray for judgment as follows:

- A. That the Court award Plaintiffs all of the relief sought in their Complaint;
- B. That the Court dismiss Amneal's counterclaims with respect to the '009 patent and Claims 6-15 of the '379 patent for lack of subject matter jurisdiction;
- C. That the Court dismiss Amneal's counterclaims asserted against Merz for lack of subject matter jurisdiction;
- D. That the Court deny Amneal's requested declaratory judgments and every other relief sought in Amneal's Amended Answer, Affirmative Defenses And Counterclaims;
- E. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur in prosecuting this action, including in responding to Amneal's counterclaims in this action, under 35 U.S.C. § 285; and
- F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Jack B. Blumenfeld*

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September 8, 2014

**CERTIFICATE OF SERVICE**

I hereby certify that on September 8, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on September 8, 2014, upon the following in the manner indicated:

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